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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,854	01/13/2004	Bin Ye	7570/80962	8530

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EXAMINER	
TIDWELL, JUDY LILLE	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/755,854	YE ET AL.	
	Examiner	Art Unit	
	Judy Lille Tidwell, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 1-4 and 13 are linking claims for Groups I-V. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-4 and 13. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 1-4 and 13 are linking claims for Groups I-V.

I. Claim 5, drawn to a method of determining whether a human female subject is at increased risk of having ovarian cancer, comprising determining the amount of EDN in a test biological sample using an immunoassay, classified in class 435, subclass 7.92.

II. Claims 6-7, drawn to a method of determining whether a human female subject is at increased risk of having ovarian cancer, comprising determining the amount of EDN in a test biological sample using surface

enhanced laser desorption/ionization mass spectrometry, classified in class 436, subclass 174.

III. Claims 8-9, drawn to a method of determining whether a human female subject is at increased risk of having ovarian cancer, comprising determining the amount of EDN in a test biological sample using PCR, classified in class 435, subclass 6.

IV. Claims 10-12, drawn to a method of determining whether a human female subject is at increased risk of having ovarian cancer, comprising determining the amount of EDN in a test biological sample, further comprising performing an additional assay for a diagnostic marker of cancer cells or other disease, classified in class 435, subclass 4.

V. Claims 14, 16-18 drawn to a method of determining whether a biological sample (blood or plasma, urine, or fluid removed from an ovary of said subject) from a patient with an elevated level of EDN is indicative of the presence of a malignant or a benign ovarian growth, comprising quantitating the amount of EDN monomer and EDN dimmer, classified in class 435, subclass 7.1.

VI. Claims 15, 16-18, drawn to a method of determining whether a biological sample (blood or plasma, urine, or fluid removed from an ovary of said subject) from a patient with an elevated level of EDN is indicative of the presence of a malignant or a benign ovarian growth, comprising quantitating the total amount of glycosylation associated with a malignant ovarian growth, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose that their methods would

be used together. The method of determining whether a human female subject is at increased risk of having ovarian cancer, comprising determining the amount of EDN in a test biological sample using an immunoassay (Group I), mass spectrometry (Group II), PCR (Group III), or an additional assay for a diagnostic marker of cancer cells or other disease (Group IV), a method of determining whether a biological sample from a patient with an elevated level of EDN is indicative of the presence of a malignant or a benign ovarian growth, comprising quantitating the amount of EDN monomer and EDN dimmer (Group V) or quantitating the total amount of glycosylation associated with a malignant ovarian growth (Group VI) are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation.

For example, a method of determining whether a human female subject is at increased risk of having ovarian cancer, comprising determining the amount of EDN in a test biological sample (Groups I-IV), requires the use of separate and distinct steps. Each invention performs their respective functions using structurally and functionally divergent material, such as an immunoassay (Group I), mass spectrometry (Group II), PCR (Group III), or an additional assay for a diagnostic marker (Group IV). Therefore, the methodology and materials necessary for determining the amount of EDN in a test biological sample differ significantly for each of the materials. For a method of determining whether a biological sample from a patient with an elevated level of EDN is indicative of the presence of a malignant or a benign ovarian growth, comprising quantitating the amount of EDN monomer and EDN dimmer (Group V) or quantitating the total amount of glycosylation associated with a malignant ovarian growth (Group VI), each of these inventions also performs their respective functions using structurally and functionally divergent material. For example, Group V requires the use of enzymes to treat the urine sample followed by a western blot using antibodies to detect the EDN protein. Group VI uses the total amount of urine protein on a SDS-PAGE gel with a staining kit to identify glycoprotein bands. Therefore, each method is divergent in materials and steps. For these reasons the inventions of Groups I-VI are patentably distinct.

Species Election

This application contains claims directed to the following patentably distinct species: blood or plasma, urine, or fluid removed from an ovary. The species are independent or distinct because the biological samples originate from different bodily fluids.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search of the literature required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Judy Lille Tidwell, PhD whose telephone number is 571-272-5952. The examiner can normally be reached on 8:00AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JLT
Art Unit 1642

MISOOK YU
PRIMARY EXAMINER